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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/966,493

09/28/2001

Joseph Lubner

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5286

27777

7590

06/01/2006

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,493	LUBER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/09/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. 6,099,859, or Smith et al. 6,194,000, or Harbit 3,108,046, in view of Joshi et al. US 5,030,447.

Cheng teaches a controlled release oral tablet comprising from 75-95% drug and up to about 40% waxes (see column 3, lines 34-49; and column 5, lines 30-36). The tablet provides both, immediate release and controlled release (see column 5, lines 22-26). The tablet further comprises fatty acid, surfactant (flow aid), and chelating agent (column 3, lines 51-60), and can further be coated with a semi-permeable membrane

comprises cellulose derivatives polymer (see column 4, lines 11-44). Cheng also discloses the tablet is prepared by compression (see column 6, lines 35-41).

Smith teaches an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of the analgesic agent (ID). The composition is in for oral administration in tablet or capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

Harbit teaches a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

Cheng, Smith or Harbit does not explicitly teach wax in powder form. Joshi teaches a tablet dosage form comprising wax in finely powdered form having size less than 500 μm such as microcrystalline wax, carnauba wax, or paraffin (column 2, lines 22-24). Thus, it would have been obvious to one of ordinary skill in the art to modify the wax in the tablet dosage of Cheng, Smith or Harbit using the finely powdered wax in view of the teaching of Joshi, because Joshi teaches a composition include one or more powder wax result in an excellent storage stable even though it includes a medicament which may degrade in a low pH environment (column 1, lines 37-40), because Cheng, Smith or Harbit teaches the use of wax in tablet dosage form comprising active agents.

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Claims 1-15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. 6,099,859, or Smith et al. 6,194,000, or Harbit 3,108,046, in view of Remon (WO 01/21155 A1) and Mueller et al. US 5,643,984.

Cheng, Smith or Harbit is relied upon for the reason stated above. The references do not explicitly teach wax in powder form. Remon discloses a rapidly disintegrating tablet comprising an active agent and wax (page 10, lines 14-18; page 19, lines 10-21). Wax includes microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). Active agents are chosen from a wide variety of known pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1).

Remon does not expressly teach the particle size of the microcrystalline wax. Mueller teaches typical microcrystalline hydrocarbon waxes having particle size within the range of about 1 μm to about 300 μm (column 2, lines 55-65). Thus, it would have been obvious for one of ordinary skill in the art to use microcrystalline wax in view of the teachings of Remon and Mueller for the composition taught by Cheng, Smith or Harbit, because Remon teaches the use of wax in tablet dosage form that disintegrate rapidly in water (page 9, lines 5-10), because Cheng, Smith or Harbit teaches the use of wax in tablet dosage form, and because Mueller teaches microcrystalline wax having particle size within the claimed range is known and typical.

Response to Arguments

Applicant's arguments filed 03/09/06 have been fully considered but they are not persuasive.

Applicant argues that there is no conclusion or reasoning of obviousness based on Harbit. In response to applicant's argument, the above 103(a) rejections include Harbit in the reasoning of obviousness.

Applicant argues that Remon does not teach wax particles. In view of applicant's argument, Remon is cited in combination of Mueller for the teaching of microcrystalline wax having the claimed particle size.

Applicant argues that the examiner appears to be using hindsight reconstruction the claimed invention, because there is no suggestion or disclosure in Remon as to the particle size of the microcrystalline wax, yet Remon does not provide any motivation let alone any disclosure of the particular particle size for the natural wax disclose therein. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of the instant claimed product. Whether the rejection is

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based on inherency under 35 U.S.C. 102, on prima facie obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Remon teaches the use of microcrystalline wax in a tablet dosage form that exhibits the claimed immediate release, the burden of proof is shifted to applicant to show that the microcrystalline wax use in Remon does not have the claimed particle size.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal stroke extending to the right.

S. Tran
Examiner
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